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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,965	03/25/2004	Dave S.B. Hoon	89212.0016	7891

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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05/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,965	HOON ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/31/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Upon considering the request of Applicants in a telephonic interview regarding returned mail, Examiner herewith vacates the previous office action.
2. Applicant's election of Group I (claims 1-25), in the reply filed on November 03, 2006 is acknowledged. The response neither provides any indication whether the election is with traverse or without traverse nor provided arguments for traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status

3. Claims 1-25 are considered for examination. Claims 26-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

Information Disclosure Statement

4. The Information Disclosure Statement filed on January 31, 2006 has been entered and considered in part.

Priority

5. This application filed on March 25, 2004 claims benefit of US provisional 60/457,895 filed on March 25, 2003.

Objection to the Specification

6. The Specification is objected because of the following informalities:
 - (i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least page 34-35, page -49) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Further it is noted that the disclosure contains no sequence listing either in the form of a paper copy or in a computer readable form. Appropriate correction is required.

Informalities

7. The following informalities are noted while examining the application:

(i) The instant specification contains a list of references on page 57-60 and on page 70-78. It is suggested that all the references put together be placed at the end of the disclosure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 13-14, 17-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Yang et al. (Clinical Cancer Res., Vol. 8, pp. 2890-2893, 2002).

Yang et al. teach a method of claim 13-14, 17, 20, 23, for detecting cancer comprising (a) providing a sample from a subject (see page 2890, col. 2, paragraph 1 under Materials and Methods section);

(b) detecting one or more DNA markers in the sample, wherein a combination of LOH and hypermethylation are indicative of cancer (see page 2891, col. 1, paragraph 1-2 under Materials and Methods section, page 2890, col. 1, abstract, page 2892, col. 1, paragraph 1, table-3).

With regard to claim 14, 19, 22, 25, Yang et al. teach that said sample is a tissue sample (see page 2890, col. 2, paragraph 1 under Materials and Methods section).

With regard to claim 18, 21, 24, Yang et al. teach that said cancer comprises breast cancer (see page 2890, col. 2, paragraph 1 under Materials and Methods section).

With regard to the claims 20, 23, Yang et al. teach that the detection of DNA markers in various stages of cancer and poor prognosis is indicative of cancer (see page 2892, col. 2, paragraph 1-2 indicating progression of cancer and poor prognosis of cancer associated with said DNA markers). Accordingly Yang et al. anticipates the instant claims.

B. Claims 13-15, 17, 19, 20, 22-23, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al. (Hepatology, Vol. 32, pp. 970-979, 2000).

Kondo et al. teach a method of claim 13, 17, 20, 23, for detecting cancer comprising (a) providing a sample from a subject (see page 971, col. 1, paragraph 1 under Materials and Methods section);

(b) detecting one or more DNA markers in the sample, wherein a combination of LOH and hypermethylation are indicative of cancer (see page 971, col. 1, paragraph 4 under Materials and Methods section, page 972, col. 2, paragraphs 1-3, page 970, col. 1, paragraph 1 (abstract), page 973, Fig. 2).

With regard to claim 14, 19, 22, 25, Kondo et al. teach that said sample is a tissue sample (see page 971, col. 1, paragraph 1 under Materials and Methods section).

With regard to claim 15, Kondo et al. teach that said LOH marker includes D10S197 (see page 972, table 2).

With regard to the claims 20, 23, Kondo et al. teach that the detection of DNA markers in various stages of cancer and poor prognosis is indicative of cancer (see page 973, table 3 (different stages of cancer and poor prognosis of cancer). Accordingly Kondo et al. anticipates the instant claims.

C. Claims 1, 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoon et al. (WO 96/29430).

Hoon et al. teach a method of claim 1, 7, 11, of detecting DNA markers (nucleic acid markers) in a sample comprising (i) providing a cell-free bone marrow sample (bone-marrow aspirate) (see at least page 5, line 28-31, page 96, line 10-23); (ii) detecting one or more DNA markers in the sample (see page 94, line 3-7, page 4, line 23-30).

With regard to claim 7-8, Hoon et al. teach that the method comprises detecting breast and melanoma cancer in a sample (see at least page 94, line 3-7).

With regard to claims 9-12, Hoon et al. teach that the method comprises detecting staging and prognosis of breast and melanoma cancer (see at least page 42, line 1-38, page 43, line 8-31, page 44, line 1-30, page 45, line 1-33). Accordingly Hoon et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 2-3, 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoon et al (WO 96/29430) in view of Anker et al. (Cancer and Metastasis reviews, Vol.18, page 65-73, 1999).

Hoon et al. teach a method for detecting DNA markers in a cancer patient's sample as discussed above in 8C, However, Hoon et al. did not specifically teach that the DNA markers as LOH, DNA hypermethylation or DNA mutation.

Anker et al. teach the detection of circulating DNA markers in plasma of cancer patients wherein Anker et al. teach that the DNA markers include LOH microsatellite markers located on chromosome 3p, hypermethylation markers such as gene p16, MGMT and mutation in KRAS gene as indicators of cancer detection and progression (see page 65, abstract, page 67, col. 2, paragraphs 1-2, page col. 1, paragraphs 1-2, col. 2, paragraph 1-2, page 69, col. 1, paragraph 1-2).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting DNA markers in cancer samples as taught by Hoon et al. with the DNA markers, including LOH, hypermethylation and mutation as taught by Anker et al. for the purpose of developing a sensitive method for detecting a cancer because Anker explicitly taught the use of said markers in cancer patients and the association of said markers in the progression of cancer (see page 65, abstract, page 69, col. 2, paragraph 1, page 71, col. 1, paragraphs 1-2 under conclusion section). An ordinary person skilled in the art would have a reasonable expectation of success that the combination of the method of Hoon et al. and the DNA markers of Anker et al. would result in a sensitive method for detecting cancer

as Anker et al. explicitly taught that the DNA markers play a major role in diagnostic and screening test for cancer and indicators of cancer detection and progression (see page 71, col. 1, paragraphs 1-2 under conclusion section) and such modification of the method is considered as obvious over the cited prior art.

B. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoon et al (WO 96/29430) in view of Fujiwara et al. (Cancer Res., Vol. 59, pp. 1567-1571, 1999).

Hoon et al. teach a method for detecting DNA markers in a cancer patient's sample as discussed above in 8C, However, Hoon et al. did not specifically teach that the DNA makers as as claimed in the instant claim 4.

Fujiwara et al. teach a method for detecting DNA markers in cell-free plasma samples in melanoma patients, wherein Fujiwara et al. disclose that said method comprises analysis of various microsatellite markers which includes D1S228 at chromosome 1p (see page 1568, col. 1, paragraph 3, col. 2, table 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting DNA markers in cancer samples as taught by Hoon et al. with the DNA markers as taught by Fujiwara et al. for the purpose of developing a sensitive method for detecting a cancer because Fujiwara et al. explicitly taught the use of microsatellite markers on different chromosomes in detecting cancer and the association of said markers in the progression of cancer (see page 1567, col. 1, abstract). An ordinary person skilled in the art would have a reasonable expectation of success that the combination of the method of Hoon et al. and the DNA markers of Fujiwara et al. would result in a sensitive method for detecting cancer as Fujiwara et al. explicitly taught that the DNA markers play a major role in

detecting cancer (see page 1567, col. 1, abstract) and such modification of the method is considered as obvious over the cited prior art.

C. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kondo et al. (Hepatology, Vol. 32, pp. 970-979, 2000) in view of Anker et al. (Cancer and Metastasis reviews, Vol. 18, page 65-73, 1999).

Kondo et al. teach a method for detecting DNA markers in a cancer patient's sample as discussed above in 8B, However, Kondo et al. did not specifically teach that the DNA hypermethylation makers as claimed in the instant claim 16.

Anker et al. teach the detection of circulating DNA markers in plasma of cancer patients wherein Anker et al. teach that the DNA markers include LOH microsatellite markers located on chromosome 3p, hypermethylation markers such as gene p16, MGMT and mutation in KRAS gene as indicators of cancer detection and progression (see page 65, abstract, page 67, col. 2, paragraphs 1-2, page col. 1, paragraphs 1-2, col. 2, paragraph 1-2, page 69, col. 1, paragraph 1-2).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting DNA markers in cancer samples as taught by Kondo et al. with the DNA hypermethylation markers as taught by Anker et al. for the purpose of developing a sensitive method for detecting a cancer because Anker explicitly taught the use of said markers in cancer patients and the association of said markers in the progression of cancer (see page 65, abstract, page 69, col. 2, paragraph 1, page 71, col. 1, paragraphs 1-2 under conclusion section). An ordinary person skilled in the art would have a reasonable expectation of success that the combination of the method of Kondo et al. and the DNA markers of Anker et al. would result in a sensitive method for detecting cancer as Anker et al. explicitly

taught that the DNA markers play a major role in diagnostic and screening test for cancer and indicators of cancer detection and progression (see page 71, col. 1, paragraphs 1-2 under conclusion section) and such modification of the method is considered as obvious over the cited prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner
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PRIMARY EXAMINER